



January 13, 2012

VIA ECF

Honorable Tonianne J. Bongiovanni, U.S.M.J.
U.S. District Court for the District of New Jersey
Clarkson S. Fisher Building & U.S. Courthouse
402 East State Street
Room 6052
Trenton, New Jersey 08608

John E. Flaherty
Partner
T. 973.639.7903
F. 973.297.3971
jflaherty@mccarter.com

Re: AstraZeneca AB, et al. v. Hanmi USA, Inc. et al.
Civ. Action No. 11-cv-00760 (JAP)(TJB)

Dear Judge Bongiovanni:

McCarter & English, LLP
Four Gateway Center
100 Mulberry Street
Newark, NJ 07102-4056
T. 973.622.4444
F. 973.624.7070
www.mccarter.com

Our firm, together with Fitzpatrick, Cella, Harper & Scinto, represent Plaintiffs (collectively, "AstraZeneca") in this action. We write, pursuant to Local Patent Rules 4.2(b), 4.3(b) and 4.4, seeking an Order striking from Defendant Hanmi's recently-filed Responsive *Markman* submissions certain newly-cited evidence (references and expert opinion) that should have been disclosed to AstraZeneca long ago, but was not. Additionally, Hanmi never sought leave to amend their disclosures, as is required by L. Pat. R. 3.7, before improperly doing so. Since the present claim construction schedule does not provide for any further submissions prior to a *Markman* hearing, AstraZeneca has been prejudiced. Hanmi's submission of its previously-undisclosed evidence contravenes the clear directive of L. Pat. R. 4.2(b), 4.3(b), 4.4 and the general spirit and purpose of the rules.¹ Accordingly, the new evidence should be stricken. In the alternative, AstraZeneca seeks an amendment of the existing schedule to permit it to respond to Hanmi's new evidence prior to any *Markman* hearing.

Factual Background

This is a patent infringement case. In accordance with the Local Patent Rules, the parties exchanged Preliminary Claim Constructions and supporting intrinsic and extrinsic evidence on August 15, 2011. Two weeks later, on August 31, 2011, the

¹ *AstraZeneca AB v. Hanmi USA, Inc.*, 2011 WL 5526009, *4, D.I. 138 at 8 (D.N.J. 2011) ("[The rules] are designed to require parties to crystallize their theories of the case early in the litigation and to adhere to those theories once they have been disclosed") (citation omitted)); *APP Pharmaceuticals, LLC v. Ameridose, LLC*, 2011 WL 6325975, *1 (D.N.J. 2011) ("local patent rules are created 'to further the goal of full, timely discovery and provide all parties with adequate notice and information with which to litigate their cases, not to create supposed loopholes through which parties may practice litigation by ambush,'" (citation omitted)).

BOSTON

HARTFORD

NEW YORK

NEWARK

PHILADELPHIA

STAMFORD

WILMINGTON

Hon. Tonianne J. Bongiovanni, U.S.M.J.
01/13/2012
Page 2

parties exchanged a list of rebuttal evidence. After a meet and confer and email and letter exchanges in compliance with L. Pat. R. 4.3, the parties filed a Joint Claim Construction and Prehearing Statement on September 14, 2011, along with all of the parties' supporting and rebuttal evidence. (D.I. 92, 92.1).

Opening *Markman* submissions were filed on November 7, 2011. (D.I. 132, 133). Hanmi's Opening *Markman* submissions included a declaration of its expert, Jerry L. Atwood, Ph.D. (L. Pat. R. 4.4, 4.5(b)).

Responsive *Markman* submissions were filed on January 6, 2012. (D.I. 174-175; 176-177). Hanmi's submission included ten previously-undisclosed exhibits and a supplemental declaration of Dr. Atwood citing to those ten new exhibits and presenting new opinions on these exhibits and another (previously-undisclosed evidence). Hanmi's responsive *Markman* brief also presented new arguments based on that new evidence. Notably, the Responsive *Markman* submissions are the last substantive filing contemplated by the Local Patent Rules before the *Markman* hearing; thus, Hanmi's late disclosure denies AstraZeneca the opportunity to respond to Hanmi's new evidence.

As explained below, Hanmi's new, previously-undisclosed evidence, presented outside of the schedule contemplated by the Rules, should be stricken, along with Hanmi's Responsive *Markman* Brief that reference the new evidence. The specific information to be stricken is shown in attached Exhibit A, which lists the previously-undisclosed exhibits, and Exhibits B and C, which are copies of the supplemental Atwood declaration and Hanmi's brief with the offending material stricken.

Argument

The Local Patent Rules govern the exchange and disclosure of claim construction evidence and set a firm and predictable schedule for litigants to follow. L. Pat. R. 4.2 ("Exchange of Preliminary Claim Construction and Extrinsic Evidence") requires that, upon the exchange of preliminary claim constructions, "each party shall also identify all intrinsic evidence, all references from the specification or prosecution history that support its preliminary proposed construction and designate any supporting extrinsic evidence..." (L. Pat. R. 4.2(b)); and "the parties shall exchange an identification of *all intrinsic evidence and extrinsic evidence* that each party intends to rely upon to oppose any other party's proposed construction..." (L. Pat. R. 4.2(c), emphasis added). Thirty days after the exchange of Preliminary Claim Constructions, the Local Patent Rules mandate that the parties file a Joint Claim Construction and Prehearing Statement which shall include, *inter alia*, "[e]ach party's proposed construction of each disputed term, together with an identification of all references from the intrinsic evidence that support that construction, and an identification of *any extrinsic evidence known to the party on which it intends to rely either to support its proposed construction or to oppose any other party's proposed construction...*" (L. Pat. R. 4.3(b), emphasis added).

Hon. Tonianne J. Bongiovanni, U.S.M.J.
01/13/2012
Page 3

The Local Patent Rules clearly envision a thorough, advance exchange of evidence at specifically set times so that each party can understand the full breadth of its adversary's available evidence. The schedule also allows each party to fully and adequately brief their position in anticipation of the *Markman* hearing.

In violation of the clear schedule set forth in the Local Patent Rules and by this Court, Hanmi waited until its January 6, 2012 Responsive *Markman* submission, to disclose evidence not disclosed in any of the parties previous claim construction exchanges. By asserting new evidence outside the prescribed period, Hanmi effectively derails this Court's goal of efficient disposition of complex patent disputes and deprives AstraZeneca of the opportunity to respond. Hanmi's actions are impermissible under the Local Patent Rules and principles of fairness and equity.

Furthermore, Hanmi never petitioned this Court for leave to amend any of its prior claim construction filings. The Local Patent Rules are clear on the procedure for amendments: "[a]mendment of any contentions, disclosures, or other documents required to be filed or exchanged pursuant to these Local Patent Rules may be made only by order of the Court upon a timely application and showing of good cause." L. Pat. R. 3.7 (emphasis in original). Thus, Hanmi's failure to seek leave from this Court to amend its disclosures violates L. Pat. R. 3.7. See Opinion and Order, *Hoffmann-La Roche Inc. v. Apotex Inc.*, CA No. 07-4417, D.I. 397 (D.N.J. Dec. 29, 2011) (failure to comply with Local Patent Rule disclosure requirements results in preclusion of reliance on new disclosures). See Exhibit D.

Other courts also have used a party's failure to abide by the disclosure timelines under the local rules as a basis for exclusion of evidence. See *Nordic Naturals, Inc. v. J.R. Carlson Laboratories, Inc.*, CA No. 07-2385 PJH, 2008 WL 2357312 at *9 (N.D. Cal. June 6, 2008).² In *Nordic Naturals*, the accused infringer sought to submit previously-undisclosed extrinsic evidence in the form of an expert declaration with its responsive claim construction brief. The district court struck the declaration because the alleged "rebuttal information" was not disclosed in the Joint Claim Construction Statement and therefore "was filed in violation of Patent Local Rules 4-2 and 4-3."³ Other jurisdictions have held similarly. See *Finisar Corp. v. DirectTV Group, Inc.*, 424 F.Supp. 2d 896 (E.D. Tex. 2006) (striking prior art and invalidity defenses for failure to disclose timely).

In defense of its untimely submissions, Hanmi's counsel has asserted to AstraZeneca's counsel that L. Pat. R. 4.5(c) does not limit what new evidence a party may rely upon in a responsive *Markman* Brief. However, Hanmi's attempted justification for its belated submission of new evidence is inconsistent with L. Pat. R.

² Although the Local Patent Rules of New Jersey were recently adopted, they are based on the Patent Local Rules of California and case law from that jurisdiction may be instructive. *King Pharmaceuticals, Inc. v. Sandoz Inc.*, 2010 WL 2015258, *4 at FN1 (D.N.J. 2010).

³ California Patent Local Rules 4-2 and 4-3 are analogs to New Jersey L. Pat. R. 4.2 and 4.3.

Hon. Tonianne J. Bongiovanni, U.S.M.J.
01/13/2012
Page 4

4.5(c), when interpreted in context with the other Rules. The statement in L. Pat. R. 4.5(c) that the parties “shall file and serve responding *Markman* briefs and any evidence supporting claim construction” does not allow a party to hold back arguments and evidence until the last minute. To interpret the rule in the way Hanmi suggests would allow any party to sandbag another with last minute submissions. Clearly, that cannot be the intent of the Local Rules.

AstraZeneca respectfully requests that the Court strike Exhibits 3-5 and 7-13 of Hanmi’s Responsive *Markman* Brief and portions of the supplemental declaration of Dr. Atwood citing to those ten new exhibits and presenting new opinions. Additionally, sections in Hanmi’s Responsive *Markman* Brief that rely on the untimely-submitted exhibits should also be stricken.

Conclusion

For all of the foregoing reasons, AstraZeneca respectfully requests that the Court strike Hanmi’s previously-undisclosed evidence (references and expert opinion) and the sections in Hanmi’s Responsive *Markman* Brief that rely on the previously-undisclosed evidence.

In the alternative, AstraZeneca respectfully requests modification to the *Markman* schedule to permit AstraZeneca to respond as appropriate to Hanmi’s previously-undisclosed evidence.

Respectfully submitted,

s/John E. Flaherty

John E. Flaherty

cc: Hon. Joel A. Pisano, U.S.D.J. (via ECF)
Counsel for record (via ECF)

Enclosures(3)